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SALIWANCHIK LLOYD & SALIWANCHIK A PROFESSIONAL ASSOCIATION PO Box 142950 GAINESVILLE, FL 32614			SALMON, KATHERINE D	
ART UNIT	PAPER NUMBER			
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/788,432	Applicant(s) PEACOCK ET AL.
	Examiner KATHERINE SALMON	Art Unit 1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 02 June 2009.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-6,8-14,16-23 and 25-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-6,8-14,16-23 and 25-33 is/are rejected.
- 7) Claim(s) 8 and 16 is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO/SB/08)
 Paper No(s)/Mail Date _____
- 4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date _____
- 5) Notice of Informal Patent Application
- 6) Other: _____

DETAILED ACTION

1. This action is in response to the papers filed on 6/02/2009.
2. Claims 1-6, 8-14, 16-23, 25-33 are pending. Claims 7, 15, and 24 have been cancelled.
3. The following rejections are newly applied. It is noted that the applicant requested an interview on p. 8 2nd paragraph of the reply. However, based on time constraints an office action is set forth below. Applicant is encouraged to call the examiner to set up an interview once the office action has been received and reviewed.
4. This action is nonfinal. It is noted that some of the art used in the following 35 USC 103(a) rejection has been previously cited. In so much as the arguments in the reply can be applied to the new rejection, the arguments have been responded to in the action following the relevant rejection.

Withdrawn Rejections and Objections

5. The claim objections made in section 8 of the previous office action is moot based upon amendments to the claims.
6. The rejection of the claims under 35 USC 103(a) made in section 9-10 of the previous office action is withdrawn based on arguments set forth in the reply. Specifically Wick et al. does not specifically teach a biofilm designed at a subsurface or groundwater site.

Claim Objections

7. Claims 8 and 16 are objected to because of the following informalities: The claims recite the abbreviation of phospholipids fatty acid as PFLA, whereas the abbreviation should be PLFA. Appropriate correction is required.

Claim Rejections - 35 USC § 112/New Matter

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 31-33 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 31-33 are rejected as failing to comply with the written description requirement. Upon review of the specification, the specification does not appear to provide support for the recitation of "isotope enriched substrate is an isotope enriched form of a contaminant present at the site" (claim 31) or "isotope enriched substrate is a substrate that is more readily utilized by a bioremediation-capable microbial organisms than by a bioremediation-incapable microbial organisms" (claim 32) or "isotope enriched substrate by a bioremediation-capable microbial organism serves to facilitate bioremediation by said bioremediation-capable microbial organism" (claim 33).

In response to the amendments, an applicant have not pointed to any particular teaching in the specification, but rather asserts that support can be found throughout the subject specification and in the claims as originally filed (p. 8 1st paragraph).

The claims as originally filed do not provide support for the newly proposed claims. The disclosure provides that after retrieval biotrap contents are analyzed for biomarkers that establish the effective in situ conditions that promote bioremediation of a particular contaminant (p. 5 lines 13-15). The disclosure provides that non-radioactive labeled substrates or contaminants can be added to the traps to stimulate a given response form the indigenous microbial community (p. 5 lines 15-20). However the disclosure does not provide support that the isotope enriched substrate is a form of the contaminant present at the site. The disclosure does not provide support that the bioremediation-capable microbial organisms are more readily utilized or serves to facilitate bioremediation.

These amendments to the claims, therefore, constitute new matter.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.

Patentability shall not be negated by the manner in which the invention was made.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 1-6, 8-14, 16-18, 21-22, and 25-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Arao et al. (Soil biology and biochemistry Vol. 31 1999 p. 1015) in view of Peyton et al. (US Patent 5641642 June 24, 1997) and Boschker et al. (Nature April 1998 Vol. 392 p. 801).

With regard to Claim 1, Arao et al. teaches a method of detecting at the site changes in soil bacteria and fungal activities (e.g. bioremediation) by measurement of the incorporation of ¹³C into phospholipids fatty acids (PLFA) abstract). With regard to step a, Arao et al. teaches contacting a community at a soil site with ¹³C labeled acetate (p. 1016 1st column last two paragraph). With regard to step c, Arao et al. teaches identifying biomarkers (e.g. phospholipids) in which the ¹³C label was incorporated (p. 1016 1st column last two paragraphs and 2nd column 2nd full paragraph). With regard

to step d, Arao et al. teaches the measurement of PLFA indicates microbial growth in the soil (1st paragraph) and therefore indicates that detection of microbes known to cause bioremediation because the presence of bacteria and fungi in the soil indicate that the soil sample contains living organisms (p. 1016 3rd paragraph).

With regard to Claims 2-3, Arao et al. teaches that the biomarkers are phospholipids (abstract).

With regard to Claims 4-5, Arao et al. teaches that the detection of these fatty acids are found in Gram-negative bacteria and only a small amount of Gram-positive bacteria therefore the biomarkers would detect a subset of microbial organisms (p. 1018 1st column last paragraph).

With regard to Claim 6, Arao et al. teaches the isotope of ¹³C (abstract).

With regard to Claim 8, Arao et al. teaches a method of identification of PLFA analysis (abstract).

With regard to Claim 9 step a, Arao et al. teaches contacting a community at a soil site with ¹³C labeled acetate (p. 1016 1st column last two paragraph). With regard to step c, Arao et al. teaches identifying biomarkers (e.g. phospholipids) in which the ¹³C label was incorporated (p. 1016 1st column last two paragraphs and 2nd column 2nd full paragraph). With regard to step d, Arao et al. teaches the measurement of PLFA indicates microbial growth in the soil (1st paragraph) and therefore indicates that detection of microbes.

With regard to Claims 10-11, Arao et al. teaches that the biomarkers are phospholipids (abstract).

With regard to Claims 12-13, Arao et al. teaches that the detection of these fatty acids are found in Gram-negative bacteria and only a small amount of Gram-positive bacteria therefore the biomarkers would detect a subset of microbial organisms (p. 1018 1st column last paragraph).

With regard to Claim 14, Arao et al. teaches the isotope of 13C (abstract).

With regard to Claim 16, Arao et al. teaches a method of identification of PLFA analysis (abstract).

However, Arao et al. does not teach a method of contacting the microbial community in subsurface site or down-well groundwater site with a sterile solid support that has been loaded with the 13C labeled acetate (step a) or incubating the solid support at the site for a period of time to establish a biofilm (step b).

With regard to Claims 1 and 9, Boschker et al. teaches a method of 13C labeling soil for PLFA analysis (p. 802 1st two paragraphs). Boschker et al. teaches that 13C can be directly injected into core samples from various sites of interest and that PLFA can be calculated (p. 804 1st column last paragraph). Therefore Boschker et al. teaches a method in which soil does not have to first be dried as in the method of Arao et al., but rather soil can be directly incubated with 13C. Therefore Boschker et al. indicates direct detection can be performed rather than detection only after drying a sample. However, Boschker et al. does not teach that this direct detection can be performed on site.

With regard to Claim 1 and 9, Peyton et al. teaches a device which permits biofilm forming microorganism to adhere to packing material (e.g. solid support) in order to analyze the microorganisms at groundwater and subsurface sites (abstract and

column 1 lines 15-25). Therefore Peyton et al. teaches a method wherein biofilms can be formed at the site of interest.

With regard to Claims 17-18 and 21-22, Peyton et al. teaches detection of microbes at groundwater or subsurface sites (column 1 lines 15-25).

With regard to Claims 25 and 28, Peyton et al. teaches that solid support comprises a perforated tube (Column 2 lines 10-11) which the acetate of Arao et al. would be loaded into in order to incorporate the 13C label into the sample.

With regard to Claims 26 and 29, Peyton et al. teaches that the tube comprises glass fibers or glass beads (column 2 lines 19-20).

With regard to Claims 27 and 30, Peyton et al. teaches incubating the tube for a period of time to establish a biofilm (abstract).

it would be *prima facie* obvious for one of skill in the art at the time of filing to modify the method of detecting biomarkers labeled with isotopes to detect microorganisms in soil samples as taught by Arao et al. to detect samples without first performing a drying step as taught by Boschker et al. and at the site of interest as taught by Peyton et al. The ordinary artisan would be motivated to detect at the site in order to determine the census of microbial growth at bioremediation sites in order to accurately know the optimal nutrients for growing desired organisms at the site of interest (column 1 lines 23-27). The ordinary artisan would be motivated to detect samples at the site of interest in order to determine the level of PLFA at the site without additional drying steps. One of ordinary skill in the art would have been motivated to contact a microbial community at a subsurface site or down-well water site with a

sterilized solid support coated with an isotope enriched surface by applying conventional methodologies. The methodology of growing and detecting biomarkers on an isotope enriched surface is known in the art by the teaching of Arao et al. It would have been obvious to combine Arao et al. with known methodologies of direct detection of soil samples and biofilm production at the site as taught by Boschker et al. and Peyton et al. with a reasonable expectation of success of producing a biofilm enriched with isotope in which the microbial community is contacted to at the site.

Response to arguments

The reply traverses the rejection. A summary of the arguments presented in the reply is set forth below with response to arguments following.

The reply asserts that Arao et al. does not teach contacting a community at a soil site, but rather teaches that the soil is removed, sieved, and stored before bringing into contact with a biofilm (p. 8 last paragraph through p. 9 1st paragraph). The reply asserts that as such Arao et al. does not teach a method adapted for in situ use (p. 9 1st paragraph).

The reply arguments toward Wick et al. are moot because the newly presented 35 USC 103 (a) are not dependent on the teachings of Wick et al. (p. 9 2nd paragraph).

The reply asserts that the methodology of Peyton et al. is to take a census of microbial growth (p. 9 last paragraph). The reply asserts that in column 1 lines 20-29, Peyton et al. indicates that the introduction of excess nutrients would produce an effect on the microbial community (p. 9 last paragraph). The reply asserts that the solid support is loaded or coated with an isotope enriched substrate and therefore would

introduce excess nutrients during the census and as such would affect the community (p. 9 last paragraph).

These arguments have been fully reviewed but have not been found persuasive.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Specifically, although, as acknowledged above, although Arao et al. does not teach a method of applying a biofilm at a site of interest, the combination of art does suggest such a methodology. Specifically Boschker et al. teaches that PLFA analysis may be performed at any point and therefore the soil sample does not have to be sieved as taught by Arao et al. Rather, Boschker et al. teaches a fresh sample may be used for PLFA analysis. Peyton et al. teaches a methodology to incubate biofilms at the site of interest. Therefore the combination of art teaches a method of contacting a biofilm at a site of interest.

The reply seems to be asserting that the method of Peyton et al. teaches methodology for the census of microbials in a site. The reply seems to be asserting that the ordinary artisan would not be motivated to contact the site with an isotope enriched support as this would affect the microbes in the immediate area of the site. However, Peyton et al. teaches a device which permits a biofilm forming microorganism to adhere to packing material in order to analyze the microorganisms at a groundwater or subsurface site. It would be obvious to use the same biofilm for PLFA analysis as

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taught by Arao et al. Further, Peyton et al. teaches that many analyses may be performed on the packing material once it was retrieved including the identity of microorganisms, quantity of biomass, physiological state of biomass, total attached solids, volatile attached solids, and nutrient requirements (column 3 lines 15-20). Therefore it would be obvious to one of ordinary skill in the art that a solid support with ¹³C could be used to create a biofilm as taught by Arao et al. at the site as taught by Peyton et al. in order to determine *in situ* changes in soil bacterial and functional activities. Further Peyton et al. teaches that the system can measure the accumulation rate of the bioremediation process (column 1 lines 60-63), as such, Peyton et al. teaches that a census can be taken not only without the introduction of excess nutrients, but in the presence of excess nutrients.

11. Claims 19 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Arao et al. (*Soil biology and biochemistry* Vol. 31 1999 p. 1015) and Peyton et al. (US Patent 5641642 June 24, 1997) and Boschker et al. (*Nature* April 1998 Vol. 392 p. 801) as applied to Claims 1-6, 8-14, 16-18, 21-22, and 25-30 and in view of Alexandrino et al. (*Applied and environmental Microbiology* October 2001 Vol 67 p. 4796).

The combination of Arao et al., Peyton et al., and Boschker et al. teaches a method of contacting a microbial community at a subsurface or down well groundwater site with a solid support loaded with an isotope enriched substrate, incubating, and

identifying biomarkers. However the combination does not teach labeling the biomarker with ^2H .

With regard to Claims 19 and 23, Alexandrino et al. teaches that ^2H can be used as a tracer for PLFA analysis (abstract).

Therefore it would have been prime facie obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Arao et al, Boschker et al., and Peyton et al. to include a label of ^2H on the biomarker for PLFA analysis as taught by Alexandrino et al. It would have been obvious to one of ordinary skill in the art at the time the invention was made to choose from a finite number of predictable isotope labels for the biomarker including ^2H with a reasonable expectation of success of labeling the biomarker in PLFA analysis for detection of the polylipids in the sample. Further Alexandrino et al. teaches that a use of ^2H for labeling is that there are a large number of compounds of ^2H available, the isotopes are less expensive, and the relatively low natural background of deuterium is beneficial for detection (p. 4796 2nd column 1st paragraph).

Response to arguments

A summary of the arguments presented in the reply is provided below with response to arguments following.

The reply asserts that the combination of Arao et al, Wick et al. and Peyton et al. does not teach a method for in situ use (p. 10 2nd paragraph). The reply presents identical arguments as cited above (p. 10 2nd paragraph).

These arguments have been fully reviewed but have not been found persuasive.

As discussed in the response to arguments section above, the combination of Arao et al. Peyton et al. and Boschker et al. teaches all the required limitations to the claims. Please see response to arguments in section 10 with regard to the response to the specific arguments set forth in the reply.

12. Claims 20 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Arao et al. (Soil biology and biochemistry Vol. 31 1999 p. 1015), Peyton et al. (US Patent 5641642 June 24, 1997) and Boschker et al. (Nature April 1998 Vol. 392 p. 801) as applied to Claims 1-6, 8-14, 16-18, 21-22, and 25-30 and in view of Kharlamenko et al. (Marine Ecology 2001 Vol. 220 p. 103).

The combination of Arao et al., Peyton et al., and Boschker et al. teaches a method of contacting a microbial community at a subsurface or down well groundwater site with a solid support loaded with an isotope enriched substrate, incubating, and identifying biomarkers. However the combination does not teach labeling the biomarker with ^{34}S .

With regard to Claims 19 and 20, Kharlamenko et al. teaches that ^{34}S can be used as a tracer for biomarkers (abstract).

Therefore it would have been prime facie obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Arao et al, Boschker et al., and Peyton et al. to include a label of ^{34}S on the biomarker for PLFA analysis. It would have been obvious to one of ordinary skill in the art at the time the invention was made to choose from a finite number of predictable isotope labels for the biomarker

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including ^{34}S with a reasonable expectation of success of labeling the biomarker in PLFA analysis for detection of the polylipids in the sample.

Response to arguments

A summary of the arguments presented in the reply is provided below with response to arguments following.

The reply asserts that the combination of Arao et al, Wick et al. and Peyton et al. does not teach a method for in situ use (p. 11 1st paragraph). The reply presents identical arguments as cited above (p. 11 1st paragraph).

These arguments have been fully reviewed but have not been found persuasive.

As discussed in the response to arguments section above, the combination of Arao et al. Peyton et al. and Boschker et al. teaches all the required limitations to the claims. Please see response to arguments in section 10 with regard to the response to the specific arguments set forth in the reply.

13. Claims 31-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Arao et al. (Soil biology and biochemistry Vol. 31 1999 p. 1015) , Peyton et al. (US Patent 5641642 June 24, 1997) and Boschker et al. (Nature April 1998 Vol. 392 p. 801) as applied to Claims 1-6, 8-14, 16-18, 21-22, and 25-30 and in view of Lytle et al. (Journal of Microbiological methods 2001 Vol. 44 p. 271).

The combination of Arao et al, Peyton et al., and Boschker et al. teaches a method of contacting a microbial community at a subsurface or down well groundwater site with a solid support loaded with an isotope enriched substrate, incubating, and

identifying biomarkers. However the combination does not teach the isotope enriched substrate is an isotope enriched form of a contaminant present at the site, the isotope enriched substrate is a substrate that is more readily utilized by a bioremediation-capable microbial organisms than by a bioremediation-incapable microbial organism, or the utilization of the isotope enriched substrate by a bioremediation-capable microbial organism serves to facilitate bioremediation by said bioremediation-capable microbial organism.

With regard to Claims 31-33, Arao et al. teaches that PLFA from 13C acetate can be used to detect changes in soil bacterial and fungal activities (abstract).

With regard to Claim 31, Lytle et al. teaches a method of using 13C labeled gram negative bacteria as a tracer for bioremediation in the subsurface (abstract). Lytle et al. teaches a method of measuring 13C which replaces 12C (p. 272 2nd column 1st paragraph). Therefore with regard to Claim 31, Lytle et al. teaches the isotope is a form of the contamination present at the site. Lytle et al. teaches measuring 13C by PLFA (p. 279 2nd column 1st paragraph).

With regard to claims 32-33, Lytle et al. teaches the phospholipids measured by PLFA provide insights in the subsurface as defining end points for bioremediation (p. 279 2nd column). Lytle et al. teaches that the measurement of trace bacteria (e.g. the measurement of the isotope) provides for the progress of remediation (p. 279 2nd column 2nd paragraph). Therefore Lytle et al. teaches that the isotope enriched bacteria provides for bioremediation of a site.

Therefore it would be *prima facie obvious* to one of ordinary skill in the art to modify the method of Arao et al. Peyton et al., and Boschker et al. to further includes a measurement of gram negative bacteria which are used fro bioremediation of the subsurface. Arao et al. teaches that gram negative bacteria can be measured by PLFA (p. 1018 1st column last paragraph). Arao et al. teaches that measurement of PLFA indications the microbial growth in the soil (p. 1016 1st paragraph). As such it would be obvious to one of ordinary skill in the art to use the isotope enriched substrate utilized by bioremediation capable microbial organisms to facilitate bioremediation as taught by Lytle et al. The ordinary artisan would be motivated to further use the microbial organism to facilitate remediation as Lytle et al. teaches that these bacteria are good indicators of the progress of remediation (p. 279 2nd column 2nd paragraph).

Conclusion

14. No claims are allowed.
15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to KATHERINE SALMON whose telephone number is (571)272-3316. The examiner can normally be reached on Monday-Friday 8AM-530PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James (Doug) Schultz can be reached on (571) 272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Katherine Salmon/
Examiner, Art Unit 1634

/JD Schultz/
Supervisory Patent Examiner, Art Unit 1635